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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,335	02/14/2002	Stephen D. Ginsberg	HO-P02202US2	8704
27123	7590	04/03/2006	EXAMINER	
MORGAN & FINNEGAN, L.L.P.			HORLICK, KENNETH R	
3 WORLD FINANCIAL CENTER			ART UNIT	
NEW YORK, NY 10281-2101			PAPER NUMBER	

1637

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/075,335	<b>Applicant(s)</b> GINSBERG ET AL.	
	<b>Examiner</b> Kenneth R. Horlick	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 59-62, 80-87 and 90-115 is/are pending in the application.
- 4a) Of the above claim(s) 59-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-87 and 90-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 03/09/06 has been entered.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 80-87 and 90-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al. (US 5,962,272) in view of Van Gelder et al. (US 5,545,522), and further in view of any one of Guatelli et al., Cleuziat et al. (US 5,849,547), or Kacian et al. (US 5,399,491).

These claims are drawn to a method of RNA amplification, comprising incubating a target strand with a synthesis primer and a terminal continuation oligonucleotide, wherein both the terminal continuation oligonucleotide and the primer comprise a transcriptional promoter sequence; extending the primer to form a first strand cDNA; incubating the first strand cDNA with the terminal continuation oligonucleotide; extending said oligonucleotide to form a second strand cDNA; incubating the cDNA with an RNA polymerase; and transcribing a plurality of sense and antisense RNA transcripts from the cDNA.

Chenchik et al. disclose a method of RNA amplification using a synthesis primer and a terminal continuation oligonucleotide (called a "CapSwitch" oligonucleotide), wherein the amplification product is double-stranded DNA (see especially Fig. 3-1 and columns 2-13). With respect to both said oligonucleotide and primer, Chenchik et al. disclose numerous modifications, including incorporation of RNA polymerase promoter sequences (column 6, lines 6-34 and column 10, lines 20-44).

While Chenchik et al. disclose modification of their basic method using oligonucleotides and/or primers comprising a transcriptional promoter sequence, they do not explicitly disclose the use of these sequences to form a plurality of sense and antisense RNA transcripts from the synthesized double-stranded cDNA. That is, the patent notes that such modifications "...simplify subsequent purification, using and cloning cDNA...".

Van Gelder et al. disclose the incorporation of a transcriptional promoter sequence on a primer for extending a target RNA sequence into a cDNA, wherein said

sequence advantageously provides for synthesis of a plurality of RNA transcripts from the cDNA using an RNA polymerase (see Figure 1 and columns 2-10). This patent does not disclose the use of a promoter sequence on both ends of a target sequence such that both sense and antisense RNA transcripts are synthesized.

Each of Guatelli et al., Cleuziat et al., and Kacian et al. disclose the advantageous incorporation of an RNA polymerase promoter on both ends of a target nucleic acid sequence such that both sense and antisense RNA transcripts are synthesized. In Guatelli et al., see pages 1874-1878, especially Fig. 1 on page 1875; in Cleuziat et al., see especially Figs. 16 and 17 and columns 18-23 and 32-33; in Kacian et al., see especially Figs. 1e-1h and columns 10-13.

One of ordinary skill in the art would have been motivated to use the embodiment of Chenchik et al. wherein both the terminal continuation oligonucleotide and the synthesis primer comprise a transcriptional promoter sequence, to form a plurality of sense and antisense RNA transcripts from double-stranded cDNA, because Van Gelder et al. disclosed the advantageous use of such a promoter sequence on one end of a target nucleic acid for that purpose, and each of the tertiary references disclosed the additional advantage of using such a promoter sequence on both ends – namely, that both sense and antisense RNA would be expressed from the construct. Besides the benefit of being useful in an amplification cycle as directly taught in the tertiary references, the skilled artisan at the time of the invention would have also recognized other advantageous uses of this construct with promoter sequences at both ends, including synthesis of sense and antisense RNA for antisense inhibition applications, as

well as synthesis of RNA probes for both strands of a target nucleic acid for detection purposes. In other words, given the teachings of Van Gelder et al. and any one of the tertiary references Guatelli et al., Cleuziat et al., and Kacian et al., the claimed methods would have been an obvious and suggested extension or application of the method of Chenchik et al., providing the expected benefit of amplified sense and antisense RNA from the cDNA. Regarding the dependent claims, these indisputably relate to well known, conventional methodologies and parameters in nucleic acid manipulation and histology, and thus clearly do not bear on patentability. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

3. Regarding the above new ground of rejection necessitated by the amendment, the arguments of the response filed 01/10/06 have been fully considered, and are moot in light of the new rejection including the cited tertiary references.


4. No claims are free of the prior art.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

03/27/06